

From the Society for Clinical Vascular Surgery

The rise and fall of renal artery angioplasty and stenting in the United States, 1988-2009

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Objective: Optimal management of renal artery stenosis (RAS) remains unclear. Recent randomized controlled trials have shown no clear benefit with percutaneous transluminal angioplasty with or without stenting (PTRAS) over medical management. We hypothesize that interventions for RAS are decreasing nationally.

Methods: The Nationwide Inpatient Sample, 1988-2009, was used to identify patients with a diagnosis of renal artery atherosclerosis undergoing open surgical repair (bypass or endarterectomy) or PTRAS. The rate of interventions, in-hospital death, and perioperative outcomes were analyzed over time. Additionally, we used individual state inpatient and ambulatory databases to better understand the influence of outpatient procedures on current volume and trends.

Results: We identified 308,549 PTRAS and 33,147 open surgical repairs. PTRAS increased from 1.9/100K adults in 1988 to 13.7 in 2006 followed by a decrease to 6.7 in 2009. Open surgical repair steadily decreased from 1.3/100K adults in 1988 to 0.3 in 2009. In 2009, PTRAS procedures (6.4/100K adults) greatly outnumbered procedures done by open repair alone (0.1/100K), combined open renal and aortic repair (0.2/100K), and combined PTRAS and endovascular aneurysm repair (0.3/100K). From 2005 to 2009 33,953 patients underwent PTRAS in the states of New Jersey Maryland, Florida, and California combined. The total number of PTRAS performed in the outpatient setting remained stable from 2005 (3.8/100K) to 2009 (3.7/100K), whereas the total number of inpatient procedures mirrored the national trend, declining from 2006 (7.9/100K) to 2009 (4.2/100K). PTRAS had lower in-hospital mortality (0.9% vs 4.1%; $P < .001$) compared with open repair. PTRAS patients were more likely to be discharged home (86.2% vs 76.3%; $P < .001$) and had a shorter length of stay (4.4 vs 12.3 days; $P < .001$). Mortality was higher after combined open renal and open aortic surgery compared to open repair alone (6.5% vs 4.1%; $P < .001$). Mortality was similar for combined PTRAS and endovascular aneurysm repair compared with PTRAS alone (1.2% vs 0.9%; $P = .04$).

Conclusions: The performance of PTRAS procedures for the management of RAS has decreased significantly after 2006. An increasing proportion of these procedures are performed in the outpatient setting. PTRAS remains the dominant revascularization procedure for RAS with lower in-hospital mortality and morbidity than surgery. (J Vasc Surg 2013;58:1331-8.)

Patient selection for renal artery stenosis (RAS) intervention remains unclear largely because of the results of several prospective randomized controlled trials (RCTs).¹⁻⁵ These RCTs, which included trials performed both before and after the shift from angioplasty alone to angioplasty with stenting (percutaneous transluminal angioplasty with or without stenting [PTRAS]), evaluated

the outcome of RAS treated medically or by PTRAS. Inclusion criteria varied for each study but included criteria such as diastolic blood pressure, creatinine clearance, and the percentage of renal artery lumen diameter reduction. Outcome variables in these studies included mortality, blood pressure control, required dosage of antihypertensive medications, renal function, and procedural complications. The data from these trials showed that there was no clear benefit for interventional treatments over medical management.

Regardless, the number of renal artery interventions had increased after the publication of these trials. National inpatient data have shown a 173% increase in catheter-based procedures from 1988 to 2001.⁶ The rate of inpatient and outpatient percutaneous renal artery intervention among Medicare beneficiaries increased 2.4-fold from 1996 to 2000.⁷ With the initial RCTs on interventional treatment vs medical management of RAS published over 10 years ago and the continuing lack of evidence regarding the optimal treatment for RAS, we wondered whether RAS treatment has plateaued, declined, or continued to rise.

The purpose of this study was to evaluate national trends in intervention for RAS using PTRAS or open surgery with and without aortic surgery. RAS encompasses both renal atherosclerosis and fibromuscular dysplasia, and treatment of these is generally considered distinct, so

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separate evaluation of these two disease processes was performed.

METHODS

Databases. The Healthcare Cost and Utilization Project is a family of health care databases including the Nationwide Inpatient Sample (NIS) and State Inpatient and Ambulatory Databases. The NIS is a 20% all-payer sample of hospital stays and contains sampling weights to allow for calculation of total population estimates. NIS data are collected from hospital discharge abstracts, which include information about all procedures performed during a given hospital admission as well as patient characteristics, comorbidities, in-hospital mortality, and length of stay. The NIS currently consists of over 8 million annual hospitalizations from 1050 hospitals in 44 states, representing approximately 95% of all hospitalizations. It is the largest all-payer inpatient care database in the United States.⁸

Many endovascular procedures have shifted to the outpatient surgery setting and data regarding outpatient procedures are not available in the NIS. However, New Jersey, Maryland, Florida, and California are a few states that make these data available in both their State Inpatient Database and their State Ambulatory Surgery Database. These databases represent a 100% sample of hospital discharges and ambulatory procedures, respectively, within each state. We analyzed the inpatient and ambulatory surgery data in these states, years 2005 to 2009, to determine the extent to which the trends seen nationally are simply a reflection of the changes in utilization of outpatient care for RAS patients.

Data retrieval—NIS. Patients were selected in the NIS, years 1988 to 2009, using diagnosis and procedure codes from the International Classification of Diseases, 9th Revision (ICD-9). Two groups of patients were studied: (1) those with a diagnosis of renal atherosclerosis and (2) those with a diagnosis of fibromuscular dysplasia (FMD).

For renal atherosclerosis, patients were required to have a primary diagnosis code for renal artery atherosclerosis (440.1) or renovascular hypertension (405.01, 405.11, 405.91) combined with a procedural code for open renal artery revascularization [endarterectomy (38.16), resection of vessel with anastomosis (38.36), resection of vessel with replacement (38.46), aortorenal bypass (39.24), and reimplantation of renal artery (39.55)] or angioplasty with or without stenting (PTRA/S) [angioplasty or atherectomy of other noncoronary vessels (39.50), other repair of vessel (39.59), or insertion of nondrug-eluting peripheral vessel stent (39.90)]. Patients with a concomitant diagnosis code for mesenteric ischemia (55.70, 55.71) or vascular trauma (902.xx) were excluded. Patients with a concomitant code for renovascular hypertension and FMD were excluded from the renal atherosclerosis group and instead classified in the FMD group.

For FMD, patients were required to have a primary diagnosis code for fibromuscular dysplasia of the renal

artery (447.3) combined with a procedural code for open renal artery revascularization or PTRA/S. Patients with a concomitant diagnosis code for mesenteric ischemia, carotid stenosis (433.10, 433.11, 433.31), or vascular trauma were excluded.

We also investigated combined procedures such as open renal artery repair with aortic surgery and PTRA/S with endovascular aneurysm repair (EVAR). Aortic surgery procedure codes included endarterectomy (38.14), resection of vessel with anastomosis (38.34), resection of vessel with replacement (38.44, 38.45), shunt or vascular bypass (39.25), and other abdominal bypass (39.26). The EVAR procedure code was 39.71. The adult population of the United States for each year was determined from U.S. Census Bureau data.⁹

Data retrieval—state databases. The inpatient and ambulatory databases of the states of New Jersey, California, Maryland, and Florida were examined. Patients were identified using ICD-9 diagnosis codes for renal artery atherosclerosis, renovascular hypertension, and FMD. With the exception of the state ambulatory databases of California and Maryland, ICD-9 procedure codes were used to identify all patients undergoing open renal artery revascularization or PTRA/S. In the state ambulatory databases of California and Maryland, current procedural terminology codes were used to identify open renal artery revascularization procedures (35341, 35536, 35636, 35560, and 35631) and PTRA/S (37205, 37207, 35450, 35471, 35480, and 35490).

Physician specialty determination. For PTRA/S, we were interested in volume trends with the following specialties: vascular surgeons (VS), interventional cardiologists (IC), and interventional radiologists (IR). NIS provides unique physician identifiers per state that allows tracking of procedures performed by that physician during that specific year. Of the available states, 27 provided two unique physician identifiers, of them 22 states specifically stated which identifier correlated with the primary procedure performed. For the remaining five states, the identifiers were only used when both were identical to make sure that it involved the physician that performed the primary procedure (the identifiers were identical in 75% of cases). We composed a list of specialty-specific procedures that we used to identify the specialty of each physician, which is included in the [Supplementary Table](#), online only. Similar approaches have been previously reported.¹⁰⁻¹² Subsequently, we created a hierarchical model: each physician that performed >10 interventional cardiac procedures was labeled an IC; physicians with >10 interventional radiology procedures were identified as IR; the remaining physicians that performed 75% to 100% vascular surgery procedures (of vascular and general surgery codes combined) and >10 in number were classified as VS. As these identifiers became available from 2001 onward, specialty-related analyses were restricted to that period.

Outcomes. Our primary outcome was procedure utilization over time. Secondary outcomes included in-hospital

Table I. Baseline characteristics of patients diagnosed with RAS or FMD undergoing PTRAS or OR from 1988 to 2008

	RAS			FMD		
	PTRAS	OR	P	PTRAS	OR	P
No.	308,549	33,147		6706	595	
Age (mean \pm SD)	70.8 \pm 10.4	66.8 \pm 9.9	<.001	58.8 \pm 15.4	48.7 \pm 12.8	<.001
Female	56.2	47.3	<.001	88.9	83.6	<.001
Hypertension	74.8	54.9	<.001	78.2	36.7	<.001
PVD	67.9	79.2	<.001	29.5	38.5	<.001
COPD	16.2	21.8	<.001	7.2	9.9	.02
Prior MI	8.2	6.5	<.001	2.9	0.7	<.01
CHF	14.1	12.4	<.001	3.6	1.7	.01
Valvular disease	8.1	4.7	<.001	5.6	4	.11
Diabetes w/o comp	22.0	10.1	<.001	8.0	5.2	.02
Diabetes w/comp	4.8	2.0	<.001	0.7	0.0	.04
Chronic renal disease	8.8	3.0	<.001	2.6	0.0	<.001
Obesity	3.2	1.6	<.001	3.3	0.0	<.001

CHF, Congestive heart failure; COPD, chronic obstructive pulmonary disease; FMD, fibromuscular dysplasia; MI, myocardial infarction; OR, open repair; PTRAS, percutaneous transluminal angioplasty with or without stenting; PVD, peripheral vascular disease; RAS, renal artery stenosis. Values are in % unless otherwise indicated.

death, postoperative complications [including stroke (997.02), cardiac complications (997.1), respiratory complications (997.3), digestive complications (997.4), genitourinary complications (997.5), vascular (997.71, 997.72, 997.79), peripheral vascular (997.2), wound disruption (998.3), postoperative infection (998.5), and hemorrhage/hematoma (998.11, 998.12)], length of stay, and discharge disposition. We excluded patients with combined procedures when analyzing outcomes after open renal artery repair alone and PTRAS alone.

Statistical analysis. Comparisons between cohorts were done using the *t*-test for parametric continuous data, and the Pearson χ^2 test for categorical and numeric data. Continuous data are presented as mean \pm standard deviation. Groups were stratified by diagnosis (renal atherosclerosis vs FMD) and by procedural method (open surgical repair vs PTRAS). Queries were performed using SAS 9.1 statistical software (SAS Institute, Cary, NC). Statistical analyses were performed using PASW 18.0 (SPSS Inc, Chicago, Ill). Population estimates are calculated by applying the sampling weight for each observation. Statistical significance was assigned at $P < .05$.

RESULTS

Patient characteristics. From 1988 to 2009, there were 308,549 PTRAS and 33,147 open surgical repairs for patients with renal atherosclerosis and 6706 PTRAS and 595 open surgical repairs for patients with FMD. The mean age was higher for patients receiving PTRAS compared with open repair for both renal atherosclerosis (70.8 vs 66.8; $P < .001$) and FMD (58.8 vs 48.7; $P < .001$) (Table I). Patients undergoing intervention for FMD were younger than those undergoing intervention for renal atherosclerosis (mean age, 59.4 vs 70.9; $P < .001$), and FMD patients were more likely to be female (87.0% vs 58.0%; $P < .001$).

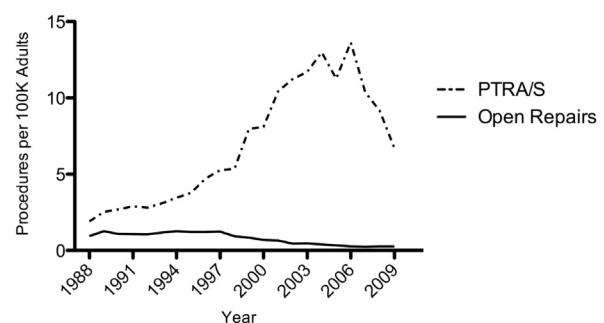


Fig 1. Annual number of inpatient procedures per 100K adults for treatment of renal artery atherosclerosis from 1988 to 2009: percutaneous transluminal angioplasty with or without stenting (PTRAS) compared with open repair.

Renal artery atherosclerosis. Over the study period, there were consistently more PTRAS repairs in patients with a diagnosis of renal atherosclerosis. PTRAS interventions increased substantially from 1988 to 2006 (1.9 to 13.7 procedures per 100K adults), followed by a marked decrease from 2006 to 2009 (13.7 to 6.7 procedures per 100K adults), whereas the number of open repairs gradually decreased throughout the study period (1.3 to 0.3 procedures per 100K adults) (Fig 1). Compared with open repair, patients undergoing PTRAS had higher rates of comorbidities except for peripheral vascular disease and chronic obstructive pulmonary disease (Table I). The mean age for PTRAS intervention increased from 62.9 years in 1988 to 71.8 years in 2009 for patients with renal atherosclerosis ($P < .001$) (Fig 2). No significant trend was seen for the mean age of open treatment of renal atherosclerosis.

From 2005 to 2009, 20,759 patients in the state inpatient databases (of New Jersey, Maryland, Florida, and

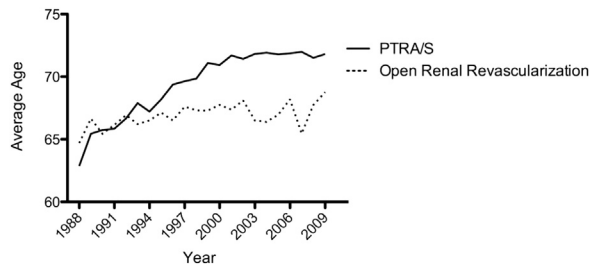


Fig 2. Change in mean age of patients undergoing inpatient percutaneous transluminal angioplasty with or without stenting (PTRA/S) or open renal artery revascularization for a diagnosis of renal artery atherosclerosis from 1988 to 2009.

California) and 13,194 patients in the state ambulatory surgery databases underwent PTRA/S for a diagnosis of renal artery atherosclerosis. The number of PTRA/S performed in the outpatient setting remained stable from 2005 (3.8/100K) to 2009 (3.7/100K), whereas the total number of inpatient procedures declined from 2006 (7.9/100K) to 2009 (4.2/100K) (Fig 3). The percentage of outpatient procedures increased from 36% in 2005 to 47% in 2009. There was no variability between states, as all four states showed a decrease in total interventions after 2006.

PTRA/S had lower overall in-hospital mortality compared with open repair (0.9% vs 4.1%; $P < .001$) (Table II). There was no significant change in the year-to-year in-hospital mortality trend from 1988 to 2009. The proportion of patients discharged home was higher (86.2% vs 76.3%; $P < .001$), and the length of stay was shorter (4.4 vs 12.3 days; $P < .001$) after PTRA/S. PTRA/S had fewer postoperative complications compared with open repair in all categories except for hemorrhage and hematoma.

Renal fibromuscular dysplasia. The change in the rate of treatment for patients with FMD was similar to that seen for patients with renal atherosclerosis. The number of PTRA/S interventions increased from 1994 to 2006 (0.1-0.3 procedures per 100K adults) and decreased from 2006 to 2009 (0.3-0.1 procedures per 100K adults) (Fig 4). Although the number of open repairs fluctuated over the study period, it consistently remained lower than PTRA/S interventions per year. Similar to patients with renal atherosclerosis, patients undergoing PTRA/S had higher rates of comorbidities except for peripheral vascular disease and chronic obstructive pulmonary disease (Table I).

From 2005 to 2009, 357 patients in the state inpatient databases (of New Jersey, Maryland, Florida, and California) and 422 patients in the state ambulatory surgery databases underwent PTRA/S for a diagnosis of FMD. The number of PTRA/S performed in the outpatient setting increased from 2005 (0.12/100K) to 2007 (0.14/100K) and declined from 2007 to 2009 (0.11/100K). The trend in inpatient procedures mirrored the trend in outpatient procedures, increasing from 2005 (0.11/100K) to 2007 (0.12/100K) and declining from 2007

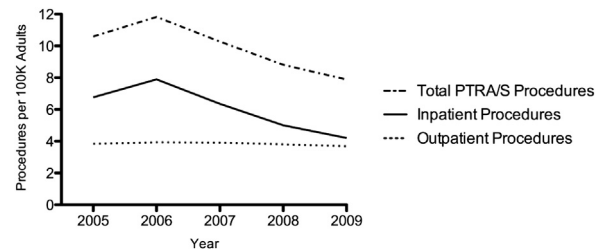


Fig 3. Annual number of percutaneous transluminal angioplasty with or without stenting (PTRA/S) procedures per 100K adults performed in New Jersey, Maryland, Florida, and California from 2005 to 2009 in patients with a diagnosis of renal atherosclerosis.

Table II. Perioperative complications and LOS after PTRA/S and OR for patients with a diagnosis of RAS

	PTRA/S	OR	P
Mortality	0.9	4.1	<.001
Discharged home	86.2	76.3	<.001
LOS, mean (SD)	4.4 (6.3)	12.3 (11.4)	<.001
Stroke	0.2	0.7	<.001
Cardiac	0.3	6.1	<.001
Respiratory	0.3	6.1	<.001
Digestive	0.2	3.9	<.001
Urinary	0.7	4.3	<.001
Vascular	0.1	0.4	.87
Peripheral vascular	0.9	1.5	<.001
Wound disruption	0.1	0.8	<.001
Postoperative infection	0.2	1.6	<.001
Hemorrhage/hematoma	5.5	5.5	1.00

LOS, Length of stay; OR, open repair; PTRA/S, percutaneous transluminal angioplasty with or without stenting; RAS, renal artery stenosis; SD, standard deviation.

Data presented as percentage unless otherwise indicated.

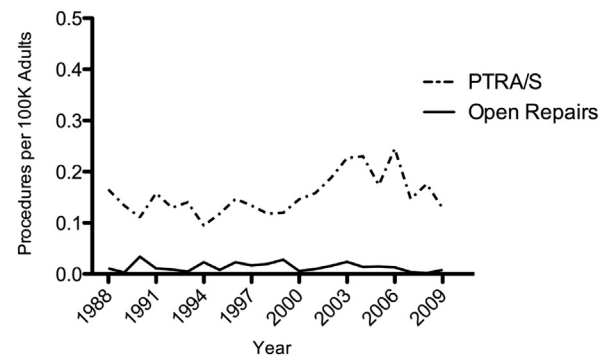


Fig 4. Annual number of procedures per 100K adults for treatment of renal fibromuscular dysplasia from 1988 to 2009; percutaneous transluminal angioplasty with or without stenting (PTRA/S) compared with open repair.

to 2009 (0.07/100K). There was no variability between states, as all four states showed a decrease in total interventions after 2007.

In-hospital mortality was significantly lower after PTRA/S compared with open repair (1.6% vs 7.8%; $P < .001$) (Table III). The proportion of patients discharged

Table III. Perioperative complications and LOS after PTRAS and OR for patients with a diagnosis of renal FMD

	PTRAS	OR	P
Mortality	1.6	7.8	<.001
Discharge home	95.8	92.6	<.001
LOS, mean (SD)	2.8 (4.0)	7.9 (5.6)	<.001
Stroke	2.3	0	.30
Cardiac	1.4	2.7	.06
Respiratory	0.8	12.5	<.001
Digestive	0.2	23.5	<.001
Urinary	1.2	7.7	<.001
Vascular	1.1	0	.21
Peripheral vascular	1.3	9	.11
Wound disruption	0.9	4.8	<.01
Postoperative infection	0	0	1.00
Hemorrhage/hematoma	5.8	5.2	.56

FMD, Fibromuscular dysplasia; LOS, length of stay; OR, open repair; PTRAS, percutaneous transluminal angioplasty with or without stenting; SD, standard deviation.

Values are in %, unless otherwise indicated.

home was higher (95.8% vs 92.6%; $P < .001$) and length of stay was shorter (2.8 vs 7.9; $P < .001$) after PTRAS. PTRAS resulted in significantly lower complication rates of respiratory (0.8% vs 12.5%; $P < .001$), digestive (0.2% vs 23.5%; $P < .001$), urinary (1.2% vs 7.7%; $P < .001$), and wound disruption (0.9% vs 4.8%; $P < .05$).

Combined procedures. From 1988 to 2009, PTRAS was the predominant procedure for treatment of renal artery atherosclerosis in the United States (Fig 5). In this outcome analysis, patients with combined open aortic and renal artery procedures and combined endovascular aortic and renal artery procedures were excluded from the categories of open renal artery repair alone and PTRAS alone, respectively. PTRAS alone greatly outnumbered the procedures done by open repair alone, combined open renal and open aortic surgery, and combined PTRAS and EVAR. Combined open renal and open aortic surgery procedures outnumbered that of open repair alone throughout the study period. Procedures done by combined open renal and open aortic surgery decreased with a trend similar to procedures done by open repair alone.

The frequency of PTRAS + EVAR continued to increase steadily after 2000, reaching a plateau between 2006 and 2009 at 0.3 procedures per 100K adults. PTRAS + EVAR surpassed both the number of procedures done by open repair alone and procedures done by combined open renal and open aortic surgery in 2006.

Overall mortality was higher after combined open renal and open aortic surgery compared with open renal repair alone (6.5% vs 4.1%; $P < .001$) (Table IV). The proportion of patients discharged home was significantly higher after open repair alone (76.3% vs 69.2%; $P < .001$). However, length of stay was similar. There were significantly more cardiac, respiratory, and urinary complications after combined open renal and open aortic surgery.

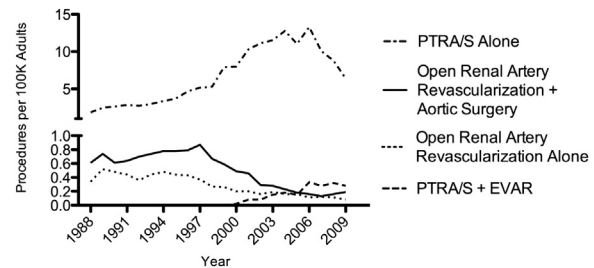


Fig 5. Annual number of inpatient procedures per 100K adults for treatment of renal atherosclerosis from 1988 to 2009 by percutaneous transluminal angioplasty with or without stenting (PTRAS) alone, open repair alone, open repair combined with open aortic surgery, and PTRAS combined with endovascular aneurysm repair (EVAR) of the aorta.

Although discharge home was less frequent after PTRAS + EVAR compared with those undergoing PTRAS alone (77.1% vs 86.2%; $P < .001$), overall mortality remained similar (1.2% vs 0.9%; $P = .04$). PTRAS + EVAR had significantly higher complications compared with patients undergoing PTRAS alone.

Physician specialty analysis. In 2001, IC performed the majority (70.8%) of all PTRAS in patients with renal artery atherosclerosis, followed by IR (16.7%), and VS (12.5%). In 2009, IC continued to perform the majority of interventions (71.3%), followed by VS (21.1%) and IR (7.6%). IC performed an increasing number of PTRAS between the years 2001 (2.8/100K) and 2006 (5.1/100K) followed by a steep decrease to 2.4/100K in 2009 (Fig 6). Similarly, VS performed an increasing number of PTRAS between 2001 (0.5/100K) and 2006 (1.4/100K) followed by a decline to 0.7/100K in 2009. IR experienced a steady decrease in procedures from 2001 (0.7/100K) to 2009 (0.3/100K).

DISCUSSION

After a rapid increase in the number of PTRAS procedures performed for the management of RAS between 1988 and 2006, a significant decrease in the number of PTRAS procedures followed. This decrease was only seen in the inpatient setting, as the number of outpatient procedures remained constant. The management of FMD was similar compared with the intervention trend for renal atherosclerosis but on a smaller scale. The increase in mean age for patients undergoing PTRAS from 1988 to 2009 may reflect an increase in the use of medical management early in renal atherosclerotic disease prior to intervention. The number of open repair procedures with or without open aortic surgery repair consistently decreased throughout the study period, reflecting a shift toward less invasive procedures. The trend toward minimally invasive procedures is further supported by an increase in the number of combined PTRAS and EVAR procedures beginning in 2000.

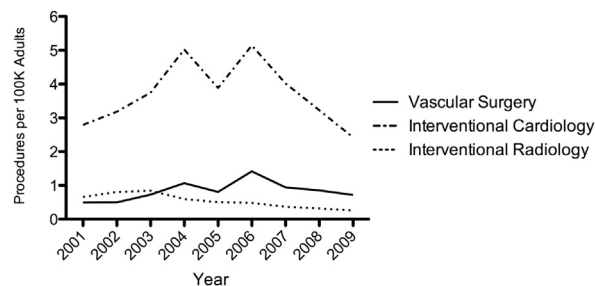
The rise in the number of PTRAS procedures performed prior to 2006 has previously been appreciated.

Table IV. Perioperative complications and LOS after OR alone, OR + AS, PTRA/S alone, and PTRA/S + EVAR for patients with a diagnosis of RAS

	OR	OR + AS	P	PTRA/S	PTRA/S + EVAR	P
Mortality	4.1	6.5	<.001	0.9	1.2	.04
Discharge home	76.3	69.2	<.001	86.2	77.1	<.001
LOS, mean (SD)	12.3 (11.4)	12.7 (45.1)	.33	4.4 (6.3)	4.2 (5.3)	<.001
Stroke	0.8	0.6	.40	0.2	0.3	.08
Cardiac	5.5	6.8	<.001	0.8	2.1	<.001
Respiratory	6.2	7.9	<.001	0.3	0.3	.76
Digestive	3.9	4.4	.05	0.2	0.9	<.001
Urinary	4.3	5.7	<.001	0.7	1.5	<.001
Vascular	0.1	0.1	.58	0.1	0.7	<.001
Peripheral vascular	1.6	1.3	.04	0.9	1.0	.56
Wound disruption	0.5	0.8	<.01	0.1	0.4	<.001
Postop infection	1.6	1.3	.07	0.2	0.4	<.01
Hemorrhage	5.5	4.0	<.001	5.5	4.5	<.01

AS, Aortic surgery; EVAR, endovascular aneurysm repair; LOS, length of stay; OR, open repair; PTRA/S, percutaneous transluminal angioplasty with or without stenting; RAS, renal artery stenosis; SD, standard deviation.

Values are in %, unless otherwise indicated.

**Fig 6.** Percutaneous transluminal angioplasty with or without stenting (PTRA/S) procedures per 100K adults performed by vascular surgeons, interventional cardiologists, and interventional radiologists from 2001 to 2009.

Studies using NIS years 1988-2001⁶ and Medicare data (1996, 1998, 2000)⁷ have previously shown a similar rapid increase in percutaneous renal artery interventions prior to 2001, but our study now reveals a reversal of this trend with a decline in percutaneous renal artery therapy after 2006. This decrease in the number of interventional treatments for RAS may be explained by a lack of demonstrated benefit of procedural intervention in recent RCTs.

Three small RCTs, all with less than 136 total patients, were published between 1998 and 2000, comparing PTSA without stenting and medical management.¹⁻³ In 1998, the Essai Multicentrique Medicaments vs Angioplastie (EMMA) study found that patients treated with angioplasty experienced more complications, but had better blood pressure control with half as many antihypertensive agents. However, blood pressure response after 6 months and renal function was not different between the treatment groups.¹ Similarly, the Scottish and Newcastle Renal Artery Stenosis Collaborative Group (SNRASC) study found no difference in blood pressure or renal function between angioplasty and medical management.³ In 2000, the Dutch Renal Artery Stenosis Intervention Cooperative (DRASTIC) trial reported no blood pressure or renal

function difference between the two treatment groups using intention-to-treat analysis but found the average daily drug dose was significantly lower in the angioplasty group.² These trials were limited by factors such as small sample size, infrequent use of stenting, inclusion of patients with only mild-to-moderate RAS (>50%-60%), and high crossover rates from medical to revascularization treatments.

The demonstration of success with renal stenting¹³ over angioplasty alone in 1999 spearheaded a number of trials to compare renal angioplasty with stenting and medical management. In 2009, the STAR trial, which included 140 patients with RAS >50%, creatinine clearance <80 mL/min, and a controlled blood pressure <140/90 mm Hg, concluded that renal stenting had no benefit over medical therapy.⁵ However, this study has been criticized because a large number of patients with mild-to-moderate renal disease and controlled hypertension were included, which under normal clinical circumstances, would not have been treated by renal artery stenting. Additionally, the criterion of RAS of >50% may include patients who do not have hemodynamically significant stenoses.

In 2009, the Angioplasty and Stenting for Renal Artery Lesions (ASTRAL) trial, enrolling a total of 806 patients, found no difference in mortality, systolic and diastolic blood pressure, vascular events, renal function, or adverse renal events between the two treatment options.⁴ However, the ASTRAL trial has also been under scrutiny and criticism; 41% of patients included in the trial had <70% stenosis, patients who the treating clinician believed would benefit from renal stenting were excluded, and there was no defined treatment regimen for medical therapy.¹⁴ The results from three other large RCTs have yet to be published; the RAVE (Renal Atherosclerotic Revascularization Evaluation) trial, the RADAR (a randomized multicenter prospective study comparing best medical treatment versus best medical treatment plus renal artery stenting in patients with hemodynamically relevant atherosclerotic renal artery stenosis) study, and the

CORAL (Cardiovascular Outcomes in Renal Atherosclerotic Lesions) trial.¹⁵ Of these trials, the CORAL trial is unique in that it is the largest and most scientifically rigorous of all the current trials.¹⁶ The weaknesses and criticisms for RCTs evaluating management of RAS are reflected in the 2005 American College of Cardiology/American Heart Association (ACC/AHA)'s lack of definitive treatment guidelines for RAS treatment and the 2006 AHRQ analysis conclusion for a need of higher-quality evidence studies for the treatment of RAS.^{17,18} These management guidelines combined with the mounting lack of evidence from RCTs to support PTRAS likely contributed to the sharp drop in the number of PTRAS starting in 2006, well before the reported results from the ASTRAL or STAR trials.

The number of open repairs, with and without aortic surgery, steadily declined throughout our study, reflecting the movement toward less invasive therapies. A retrospective study, evaluating renal angioplasty, stent placement, and bypass grafting, concluded that these procedures were all equally efficacious for control of renovascular hypertension, but the initial treatment cost for bypass grafting was significantly higher than that for angioplasty and stenting.¹⁹ However, the ACC/AHA guidelines do recommend the use of surgical intervention in certain clinical situations. This includes patients with FMD exhibiting macroaneurysms or complex disease that extends into the segmental arteries, patients with atherosclerotic RAS exhibiting multiple small renal arteries or early primary branching of the main renal artery, and patients with atherosclerotic RAS in combination with pararenal aortic reconstruction (in the treatment of aortic aneurysms or severe aortoiliac occlusive disease).¹⁷ Despite the various situations where open revascularization with or without open aortic surgery has been indicated, our data have shown that the majority of interventions for RAS have shifted away from open repair.

Because of the growing popularity in EVAR procedures, we hypothesized that there would be a growing movement toward combined PTRAS and EVAR procedures (PTRAS + EVAR) for patients with both renal artery and aortic disease. The first two EVAR stent grafts to be approved by the U.S. Food and Drug Administration occurred in September 1999 and the ICD-9 code for EVAR was subsequently introduced in 2000. Thereafter, the number of combined PTRAS + EVAR procedures has continued to rise. Our results demonstrate that PTRAS + EVAR procedures resulted in higher postoperative complications compared with PTRAS alone, as expected due to the increased procedural complexity and disease severity for patients undergoing combined procedures. We expect that the number of combined minimally invasive procedures will continue to increase in the future.

IC, IR, and VS have all been involved with the procedural treatment of RAS. We found a decrease in the number of PTRAS procedure performed for all three specialties after 2006, reflecting a universal movement away from PTRAS. However, it is clear that IC continue to perform the largest number of PTRAS for RAS.

The limitations to this study are inherent to studies using administrative data, such as the accuracy of hospital coding of comorbidities and complications. Alterations in coding methods in the NIS are therefore a potential for error, and in some instances, makes it difficult to differentiate perioperative complications from pre-existing conditions. Diagnosis codes may have been selected by clinical or financial importance, thereby explaining the fact that a lower proportion than expected of patients, particularly patients with open surgery intervention, had a diagnosis code for hypertension. There was no randomization between treatment options in this study, and the selection of treatment method was at the treating physician's discretion. However, our primary objective was to document changes in utilization of PTRAS and open surgery for RAS. In this regard, the NIS is an ideal tool. We had access to outpatient data from four states that may not accurately reflect the entirety of the United States. However, the results in these diverse states were similar and the inpatient utilization represented by the NIS was corroborated by inpatient data from these states.

The NIS allows for evaluation of a large patient sample. Therefore, we are able to draw strong conclusions in the trend of RAS treatment in the United States. We ultimately conclude that interventions for RAS have declined since 2006, likely because in part of a lack of demonstrated benefit in RCTs. Analysis of the State Inpatient and Ambulatory Surgery databases have shown that this decrease in PTRAS seen nationally is only found in the inpatient setting while outpatient procedures have remained stable. Nevertheless, as interventions have decreased nationally, PTRAS remains the dominant procedural option compared with open interventions because of its lower rate of mortality and morbidity.

AUTHOR CONTRIBUTIONS

Conception and design: PL, RH, RB, AH, MW, EC, MS
Analysis and interpretation: PL, RH, RB, AH, MW, EC, MS

Data collection: PL, RH, RB

Writing the article: PL, RH, RB, MS

Critical revision of the article: AH, MW, EC

Final approval of the article: PL, RH, RB, AH, MW, EC, MS

Statistical analysis: PL, RH, RB

Obtained funding: MS

Overall responsibility: MS

PL and RH contributed equally to this work.

REFERENCES

1. Plouin PF, Chatellier G, Darne B, Raynaud A. Blood pressure outcome of angioplasty in atherosclerotic renal artery stenosis: a randomized trial. *Essai Multicentrique Medicaments vs Angioplastie (EMMA) Study Group. Hypertension* 1998;31:823-9.
2. van Jaarsveld BC, Derx FH, Krijnen P, Pieterman H, Man in't Veld AJ, Woittiez AJ, et al. 'Hypertension resistant to two-drug treatment' is a useful criterion to select patients for angiography: the

- 'Dutch Renal Artery Stenosis Intervention Cooperative' (DRASTIC) study. *Contrib Nephrol* 1996;119:54-8.
3. Webster J, Marshall F, Abdalla M, Dominiczak A, Edwards R, Isles CG, et al. Randomised comparison of percutaneous angioplasty vs continued medical therapy for hypertensive patients with atheromatous renal artery stenosis. Scottish and Newcastle Renal Artery Stenosis Collaborative Group. *J Hum Hypertens* 1998;12:329-35.
 4. Wheatley K, Ives N, Gray R, Kalra PA, Moss JG, Baigent C, et al. Revascularization versus medical therapy for renal-artery stenosis. *N Engl J Med* 2009;361:1953-62.
 5. Bax L, Woittiez AJ, Kouwenberg HJ, Mali WP, Buskens E, Beek FJ, et al. Stent placement in patients with atherosclerotic renal artery stenosis and impaired renal function: a randomized trial. *Ann Intern Med* 2009;150:840-8; W150-841.
 6. Knipp BS, Dimick JB, Eliason JL, Cowan JA, Henke PK, Proctor MS, et al. Diffusion of new technology for the treatment of renovascular hypertension in the United States: surgical revascularization versus catheter-based therapy, 1988-2001. *J Vasc Surg* 2004;40:717-23.
 7. Murphy TP, Soares G, Kim M. Increase in utilization of percutaneous renal artery interventions by medicare beneficiaries, 1996-2000. *AJR Am J Roentgenol* 2004;183:561-8.
 8. The Healthcare Cost and Utilization Project Nationwide Inpatient Sample (NIS). Available at: <http://www.hcup-us.ahrq.gov/nisoverview.jsp>. Accessed July 6, 2011.
 9. United States Census Bureau. Available at: <http://www.census.gov/popest/>. Last accessed August 8, 2011.
 10. Csikesz NG, Simons JP, Tseng JF, Shah SA. Surgical specialization and operative mortality in hepato-pancreatic-biliary (HPB) surgery. *J Gastrointest Surg* 2008;12:1534-9.
 11. Schipper PH, Diggs BS, Ungerleider RM, Welke KF. The influence of surgeon specialty on outcomes in general thoracic surgery: a national sample 1996 to 2005. *Ann Thorac Surg* 2009;88:1566-72; discussion: 1572-3.
 12. Vogel TR, Dombrowski VY, Carson JL, Haser PB, Graham AM. Lower extremity angioplasty: impact of practitioner specialty and volume on practice patterns and healthcare resource utilization. *J Vasc Surg* 2009;50:1320-4; discussion: 1324-5.
 13. Bax L, Mali WP, Buskens E, Koomans HA, Beutler JJ, Braam B, et al. The benefit of Stent placement and blood pressure and lipid-lowering for the prevention of progression of renal dysfunction caused by atherosclerotic ostial stenosis of the renal artery. The STAR-study: rationale and study design. *J Nephrol* 2003;16:807-12.
 14. Sarac TP. Influence and critique of the ASTRAL and CORAL Trials. *Semin Vasc Surg* 2011;24:162-6.
 15. Fleming SH, Hansen KJ. Randomized clinical trials regarding management of atherosclerotic renovascular disease. *Semin Vasc Surg* 2010;23:156-64.
 16. Seddon M, Saw J. Atherosclerotic renal artery stenosis: review of pathophysiology, clinical trial evidence, and management strategies. *Can J Cardiol* 2011;27:468-80.
 17. Hirsch AT, Haskal ZJ, Hertzner NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *Circulation* 2006;113:e463-654.
 18. Balk E, Raman G, Chung M, Ip S, Tatsioni A, Alonso A, et al. Comparative effectiveness of management strategies for renal artery stenosis. Rockville, MD: Agency for Healthcare Research and Quality; October 24, 2006.
 19. Xue F, Bettmann MA, Langdon DR, Wivell WA. Outcome and cost comparison of percutaneous transluminal renal angioplasty, renal arterial stent placement, and renal arterial bypass grafting. *Radiology* 1999;212:378-84.

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Supplementary Table (online only). International Classification of Diseases, 9th Revision (ICD-9) procedure codes used to identify the physician specialty of vascular surgeons, general surgeons, interventional cardiologists, and interventional radiologists

Vascular surgeon

- 38.12 Carotid endarterectomy
- 39.29 Peripheral vascular bypass
- 84.15 Below-knee amputation
- 84.17 Above-knee amputation

General surgeon

- 17.11-24, 53.00-9 Hernia repair
- 47.01-19 Appendectomy
- 51.21-24 Cholecystectomy

Interventional cardiologist

- 00.66, 36.01-02, 36.05 Percutaneous transmural coronary angioplasty
- 36.04 Intracoronary thrombolysis
- 36.06-07 Intracoronary stenting
- 37.21-23 Heart catheterization

Interventional radiologist

- 33.26 Closed lung biopsy
 - 39.1 Transjugular intrahepatic portosystemic shunt
 - 50.11 Closed liver biopsy
 - 55.03-04 Percutaneous nephrostomy
 - 78.49, 81.65 Percutaneous vertebroplasty
 - 99.25 Chemoembolization
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